

PATENT COOPERATION TREATY

04 MAR 2005

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REC'D 29 DEC 2004

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 2002.017 WO | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416) | |
| International application No. PCT/EP 03/10696 | International filing date (day/month/year) 19.09.2003 | Priority date (day/month/year) 20.09.2002 |
| International Patent Classification (IPC) or both national classification and IPC C07K14/45 | | |
| Applicant AZKO NOBEL N.V. et al. | | |

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| 1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. |
| 2. This REPORT consists of a total of 4 sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of sheets. |
| 3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the opinion II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the International application VIII <input type="checkbox"/> Certain observations on the International application |

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| Date of submission of the demand 26.03.2004 | Date of completion of this report 27.12.2004 |
| Name and mailing address of the International preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized Officer Schwachtgen, J-L Telephone No. +49 89 2399-8933  |

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No.

REC'D 29 DEC 2004

PCT/EP 03/10696 PCT

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-33 as originally filed

Sequence listings part of the description, Pages

1-15 as originally filed

Claims, Numbers

1-20 as originally filed

Drawings, Sheets

1/28-28/28 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/EP 03/10696**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|--------------|
| Novelty (N) | Yes: Claims | 1-17, 19, 20 |
| | No: Claims | 18 |
| Inventive step (IS) | Yes: Claims | 1-17, 19, 20 |
| | No: Claims | 18 |
| Industrial applicability (IA) | Yes: Claims | 1-20 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP 03/10696

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: WO 98/37185 A (HU SHI XUE ;UNIV TEXAS (US); XU HONG JI (US); ZHOU YUNLI (US); LOG) 27 August 1998 (1998-08-27)

D3: WO 00/66154 A (ZUTHER ELLEN ;LYONS RUSSELL (GB); ROBERTS CRAIG (GB); ROBERTS FION) 9 November 2000 (2000-11-09)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 18 is not new in the sense of Article 33(2) PCT.

The document D1 discloses a DNA fragment comprising a heterologous protein, ie p53, rb, TNF or a truncated part thereof, fused to the N-terminal part of a tet-repressor protein (Claims 3 and 20-28; Examples). The disclosure in D1 anticipates all the features of the subject-matter of claim 18 of the present application. Even if novelty could be established, the subject-matter of claim 18 would represent an obvious modification (Article 33(3) PCT) of the disclosure in D1 as a solution to the problem of providing an alternative DNA fragment comprising a heterologous protein fused to the N-terminal part of a tet-repressor protein

3. D2 is regarded as being the closest prior art to the subject-matter of claims 1-17 and 19-20. D2 discloses a live attenuated parasite having knocked out essential genes from which the subject-matter of the present application differs by the use of a conditional inducible knockout of a ribosomal protein gene.

None of the cited prior art documents, either alone or in combination, appear to disclose the subject-matter of said claims, which thus meet the requirements of Article 33(3) PCT.